From

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To

Member-Secretary

Institutional Human Ethics Committee

Annoor Dental College & Hospital

Muvattupuzha

Madam/ Sir,

**Sub: Application for Ethical Review of Research Proposal**

I hereby request you to kindly place the enclosed application form and research proposal for ethical review before the IHEC of Annoor Dental College & Hospital, Muvattupuzha.

Title of the proposed project:

Name of the Principal Investigator:

Name of Guide:

Thanking you,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Principal Investigator

**Research Protocol Submission Form**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Research Protocol Number: | | | | | | |
| Title of the study: | | | | | | |
| Name of the Principal Investigator | | | **Department** | | | **Designation** |
|  | | |  | | |  |
| Contact Information of the Principal Investigator | | | | | | |
| Mobile Number |  | | | **Email ID** |  | |
| 1. Affiliation of the Principal investigator (Institution attached) | |  | | | | |
| 1. Address for communication (Investigator) | |  | | | | |
| 1. Details of Guides and Co-guides, if any | |  | | | | |
| 1. Details of collaboration with other institutions, if any | |  | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name, affiliation and qualifications of research investigators** | | | | | | | | | | | | | | | | | | |
| **Sl. No.** | Name of the Investigators | | | | | | | Qualifications (with subject) | | | | | | | | Role in the proposed study\* | | |
| **(i)** |  | | | | | | |  | | | | | | | |  | | |
| **(ii)** |  | | | | | | |  | | | | | | | |  | | |
| **(iii)** |  | | | | | | |  | | | | | | | |  | | |
| **\* Roles and responsibilities of investigators: choose the appropriate codes (A to T) below and write them against their name in the appropriate column above.** | | | | | | | | | | | | | | | | | | |
| A. Concept  B. Design  C. Screening of patients  D. Selection and recruitment of study participants  E. Informed consent  F. Selection & Recruitment of patients  G. Laboratory investigations  H. Laboratory report interpretation  I. Treatment decision  J. Patient evaluation | | | | | | | | | | K. SAE evaluation and reporting  L. Examination of patients on follow-up  M. Data collection and monitoring of data  N. Interpretation of data  O. Statistical analysis & Interpretation  P. Maintaining patients file and master file of project  Q. Drafting final report  R. Submission of final report to funding agency and IHEC  S. Publication  T. Any other, please specify | | | | | | | | |
| **Funding: Tick (✓) all that are applicable** | | | | Self-funded | | | | | Extramural Funding | | | | | | | | Intramural Funding | |
| **If funded, contact Address of Sponsor:** | | | | | | | | | | | | | | | | | | |
| **Clinical Trials: Yes**   **/ Not Applicable**  **If Yes does the study involve use of:** | | | | | | | | | | | | | | | | | | |
| **Drug** | | Devices | | | Vaccine | Alternate system of Medicine | | | | | | | Any Other (specify): | | | | |  |
| **Is it approved and marketed in?** | | | | | India | | | | | | | Other countries (specify): | | | | | | |
| **Duration of study:** | | | | |  | | | | | | | | | | | | | |
| **Does the study involve vulnerable population?** | | | | | **If Yes, mention Category:** | | | | | | | | | | | | | |
| **Informed Consent** | | | | | | | | | | | | | | | | | | |
| **Who will obtain consent?** | | | **PI**  / Co-PI | | | | Research Staff | | | | | | | Other (Specify) | | | | |
| **If consent is not applicable to your research project / study, please submit a waiver of consent application form and confidentiality statement to IHEC** | | | | | | | | | | | | | | | | | | |
| **Risks & Benefits** | | | | | | | | | | | | | | | | | | |
| Poetential risks involved in the study: | | | | | | | | | | | | | | | | | | |
| Benefits of the study: | | | | | | | | | | | | | | | | | | |
| **Conflict of Interest** | | | | | | | | | | | | | | | | | | |
| (i) Do you have conflict of interest?  (financial/nonfinancial)  (ii) If Yes, specify: | | | | | | | | | | | Yes | | | | No | | | |
| **Storage and archival of study documents** | | | | | | | | | | | | | | | | | | |
| Specify the period & site of storage of the project documents | | | | | | | | | | |  | | | | | | | |
| **Dissemination of study result** | | | | | | | | | | | | | | | | | | |
| Proposal plan for reporting and dissemination of study results (Tick [✓] all that are applicable) | | | | | | | | | | | **Peer-reviewed scientific journals** | | | | | | | |
| Conference presentation | | | | | | | | | | | Internal report | | | | | | | |
| Submission to regulatory authorities | | | | | | | | | | | Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators | | | | | | | |
| Others | | | | | | | | | | |  | | | | | | | |
| **Publication of proposed research** | | | | | | | | | | | | | | | | | | |
| Journal of choice | | | | | | | | | | |  | | | | | | | |
| Impact factor | | | | | | | | | | |  | | | | | | | |
| Indexing | | | | | | | | | | |  | | | | | | | |
| **Authorship** | | | | | | | | | | | **Contribution** | | | | | | | |
| 1st | | | | | | | | | | |  | | | | | | | |
| Corresponding Author | | | | | | | | | | |  | | | | | | | |
| 2nd | | | | | | | | | | |  | | | | | | | |
| Others | | | | | | | | | | |  | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Item Description (List of Enclosures)** | | | | | | | |
|  | | | | **Yes** | | **No** | **NA** |
| 1. Covering Letter | | | |  | |  |  |
| 1. Brief description of proposal (Format attached below) | | | |  | |  |  |
| 1. Informed Consent form (in English/ regional languages) | | | |  | |  |  |
| 1. Waiver of consent | | | |  | |  |  |
| 1. Confidentiality agreement signed by ALL investigators | | | |  | |  |  |
| 1. Copy of questionnaire (in English/ translated version in regional language) | | | |  | |  |  |
| 1. Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from other departments | | | |  | |  |  |
| 1. CV of ALL Investigators (including Guide) | | | |  | |  |  |
| 1. Declaration form | | | |  | |  |  |
| 1. Other (specify): | | | |  | |  |  |
| **Signature of PI** | | | | | | | |
| Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.  Name:  Designation, Department & Name of the Institution:    Date: Signature of PI | | | | | | | |
| **Signature of co-investigators** | | | | | | | |
| **S No.** | **Name** | **Designation** | **Institution** | | **Signature** | | |
|  |  |  |  | |  | | |
|  |  |  |  | |  | | |
| **Name and Signature of the Research Guide** | | | | | | | |
| I have reviewed this project proposal and consent to guide this project.  Name of the Guide:  Designation, Department:  Date: Signature of the Guide | | | | | | | |

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| **Permission Letters** |
| **Permission to collect data from departments (attach permission letters in separate sheet). Write below the names of departments and institutions from where samples are to be collected. It is the responsibility of the PI to obtain permission from every department of Annoor Dental College involved in data collection (and heads of departments as well as institutions, if samples are collected and/or diagnostic or imaging services are used from the respective departments / institutions) by furnishing all necessary information (including purpose, sample size, cost involved, etc., to the heads of the departments concerned).** |
| **Department/s of study:** |
| **Head of the Department** |
| I am forwarding the above project submitted by ………………………………………… Principal Investigator from my Department. I endorse the project and have ‘no objection’ for submission for consideration by the IHEC.  I concur with the participants / investigators included in the study.  The department has adequate facilities to carry out this study and the investigators(s) is/ are permitted to use the facilities available in this department to carry out the study.  Name of the Head of the Department:  Signature of the Head of the Department with date: |
| **Permission to carry out the study elsewhere (outside ADC): Yes / No / NA** |

**Note: If study will be conducted fully or partially outside the ADC, please describe the need, permission from institution(s), health centre (s), local government / administrative bodies, etc. Attach permission letters obtained already, if any.**

**DECLARATION FORM**

|  |  |  |
| --- | --- | --- |
|  | Please tick as applicable |  |
|  | I/We certify that the information provided in this application is complete and correct |  |
|  | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |  |
|  | I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines. |  |
|  | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |  |
|  | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol. |  |
|  | I/We declare that the expenditure in case of injury (Serious Adverse events) related to the study will be taken care of |  |
|  | I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed |  |
|  | I/We confirm that we will maintain accurate and complete records of all aspects of the study |  |
|  | I/We will protect the privacy of participants and assure confidentiality of data and biological samples. |  |
|  | I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study. |  |
|  | I/We declare/confirm that all necessary government/institutional approvals will be obtained as per requirements wherever applicable |  |
|  | Name of PI**:**  Dated Signature    Name of Co-PI: Dated Signature  Name of Guide: Dated Signature | |